PhRMA

*Pharmaceutical Research and Manufacturers of America*
1100 15th Street, NW, Washington, DC 20005 Tel: 202/835-3400

June 5, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, Maryland 20852

**Re: Docket No. 00N-1256**
**FDA Regulation of OTC Drug Products Hearing**

**NOTICE OF PARTICIPATION**

Pursuant to the notice of public hearing published at 65 Fed. Reg. 24704 (April 27, 2000), the undersigned hereby requests an opportunity to participate in the hearing to be held on June 28-29, 2000, in Docket No. 00N-1256, concerning FDA regulation of over-the-counter drug products, and provides the following information:

Name: Russel A. Bantham

Address: 1100 Fifteenth Street, N.W.
Washington, DC 20005

Telephone number: 202-835-3400

Affiliation and sponsor: Pharmaceutical Research and Manufacturers of America

Summary: Testimony will concern the role of the sponsor in the Rx-OTC switch process. FDA cannot use rulemaking to switch a drug over the objection of the sponsor and must respect the sponsor's proprietary rights in the safety and effectiveness data submitted in an NDA.

Time requested: 10 minutes

Respectfully submitted,

Russel A. Bantham
General Counsel and Sr. Vice President

00N-1256

APE 63